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Liquid formulation of interferon-beta
Patent Assignee: RENTSCHLER BIOTECHNOLOGIE GMBH (RENT)
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Number of Countries: 025 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 9915193	A1	19990401	WO 98EP6065	A	19980923	199920 B
AU 9896276	A	19990412	AU 9896276	A	19980923	199934
EP 1017413	A1	20000712	EP 98950074	A	19980923	200036
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Patent Details:

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AU 9896276	A				Based on patent WO 9915193
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Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE					

Abstract (Basic): WO 9915193 A1

NOVELTY - Stable interferon-beta (I) solution of neutral or slightly acid pH (pH 5-8) is new.

DETAILED DESCRIPTION - Liquid formulations of human (I), that retain at least 80% of in vitro biological activity after storage for 3 months at 25 degrees Centigrade, contain up to 25 MU (units)/ml of (I), are buffered to pH 5-8, preferably over 5.5, and are free of human serum albumin (HSA); are buffered to pH 6-7.2 and are free of HSA, or are buffered to pH 5-8, preferably over 5.5, and contain at least one amino acid.

ACTIVITY - Antiviral; antiproliferative; immunomodulatory.

MECHANISM OF ACTION - None given.

USE - Interferons are known as antiviral, antiproliferative and immunomodulatory agents.

ADVANTAGE - The formulations have high stability (of biological activity and of molecular and physical integrity); eliminate the expense of freeze-drying and reconstitution, and do not require potentially hazardous additives (serum albumin or detergents). They may even be stored for a month at 37 degrees Centigrade and still retain at least 70% of biological activity. A formulation, of pH 7, contained 50 mM sodium phosphate, 50 mg/ml glycerol, 2 mM methionine and 12.5 MU/ml (I). After 6 months storage at 25 degrees Centigrade, recovery of biological activity (assessed conventionally by inhibition of the cytopathic effect of a virus) was 13.4 MU/ml, i.e. 107.2% of the initial value and 172% of a control that had been stored for 6 months at -20 degrees Centigrade.

pp; 51 DwgNo 0/0

Title Terms: LIQUID; FORMULATION; INTERFERON; BETA

Derwent Class: A96; B04

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